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WOLF, BLOCK, SHORR AND SOLIS-COHEN LLP
250 PARK AVENUE
10TH FLOOR
NEW YORK, NY 10177

EXAMINER	
RAE, CHARLESWORTH E	
ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO@WOLFBLOCK.COM

Office Action Summary	Application No.	Applicant(s)	
	10/595,709	GRASES FREIXEDAS, FELICIA	
	Examiner	Art Unit	
	CHARLESWORTH RAE	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Corrected Form 326*.

DETAILED ACTION

Applicant's arguments/amendment, filed 2/5/08, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of actions being applied to the instant application.

Applicant is required to submit an information disclosure statement listing the post art references which were submitted as attachments to the response filed 2/5/08.

It is noted that the claim amendment canceling claims 1-7 renders the rejections of record moot with respect to these claims. As discussed below, claim 8 was inadvertently excluded from the Office action, mailed 10/5/07. To the extent that claim 8 would have been reasonably rejected in view of the cited reference (Znaiden et al.), the rejection of record is hereby amended to correct the inadvertent mistake by amending show claim 8 as being rejected. Thus, the correct status of instant claim 8 is "amended," instead of "new." A corrected Form 326 is attached to show the status of claims 1-8.

Applicant is required in the next communication to the Office to file a supplemental amendment to show the corrected status of claim 8 as "previously amended" in order to properly reflect the status of claim 8.

This action is made final. The new basis of rejections are necessitated by the amendment of the claims to recite specific active method steps wherein the terms "an

effective amount" and the term "damage zone" reasonably narrow the scope of the claims and the addition of new claims 14-19.

Status of the Claims

Claims 8-19 are currently pending in this application and are the subject of the Office action.

Claims 1-7 are canceled.

Claims 8-13 are actually amended claims and claims 14-19 are new claims.

Claims 14-19 are new claims.

claims are pending for prosecution on the merits. Claims 8-13 are actually amended claims and claims 14-19 are new claims. Anyway, since your rejection addressed all the limitations recited in the original claims 8-13 (which were not included in the previous rejection), you could make final in this rejection. Please restate your reasoning. Thanks.

Priority Claim

Receipt of the English translation of the certified copy of the foreign application, received 2/6/08, is acknowledged.

Information Disclosure Statement

Applicant is required to submit an information disclosure statement listing the post art references that were submitted as attachments to the Response of 2/2/08.

Response to applicant's arguments/remarks

Rejection under 101

This rejection is rendered moot by the claim amendment.

Rejection under 102(b)

Applicant contends that this rejection should be withdrawn for essentially the following captioned section (see applicant's Response, filed 2/6/08, at pages 5-6):

> Znaiden only mentions the use of phytate on the skin. The phytate as taught by Znaiden is used specifically over spider veins and does not mention or suggest the capacity of phytate for being absorbed through the skin, passing into the bloodstream, and acting on pathological calcification. For example, on Column 3, lines 7-11, of Znaiden, it is stated that "[t]he hydroxyl groups may allow the molecule to readily penetrate the most superficial layers of skin which are slightly polar because they lack a significant phospholipid concentration." Column 3, lines 18-24, recites:
>
> > [o]nce a highly polar molecule reaches viable tissue, it will be repulsed by cell membrane phospholipids and remain in the intracellular space. Instead of being lost through dissipitation, the molecules remain sequestered and form a stable depot, which creates a high osmotic gradient necessary for the collapse of an offending vessel.
>
> The myo-inositol of the present invention is not limited to an active location on the surface of the skin. Instead, the myo-inositol is absorbed by the skin and enters the patient's bloodstream. On page 5, lines 15-20, of the specification, it is stated that "[s]urprisingly, the inventors of this invention have found that phytate, with a high negative charge, can be absorbed by the skin when it is administered topically, passing through into the bloodstream and acting on the damaged zone (in which a heterogeneous nucleant would have been generated)."
>
> As Znaiden does not teach a method of treatment or prevention wherein the phytate is absorbed through the skin into the bloodstream, as disclosed in new Claims 8-19, and does not disclose every element of the claims, Applicants respectfully request the Examiner reconsider and withdraw the rejection under 35 U.S.C. §102(b).

In response, the rejection is maintained with respect to claim 8 as applicant's arguments are not found to be persuasive for the reasons previously made of record in the Office action, mailed 10/5/07, at pages 3-4 and for the additional reasons:

1) The term “an effective amount of myo-inositol hexaphospahte, wherein said myo-inositol hexaphosphate can be absorbed by the skin, passing into the bloodstream and acting on the damaged zone ”given its broadest reasonable interpretation, is construed to be the functional equivalent of the method taught by Znaiden et al. for treating telangiectasia which comprising the topical application of a composition to an area affected by telangiectasia, wherein said composition includes an effective amount of a member selected from the group consisting of inositol phosphoric acid, its sulfuryl derivative and its carboxyl derivative and mixtures thereof in the range from about 3 percent to about 100 percent (see reference claim 1) as the recitation of the term "effective amount" as recited in instant claim 8 is not so related to the preamble to be reasonably limited to an effective amount for treating a disease associated with the development of calcifications in soft tissue.”

2) The term “a disease associated with the development of calcifications in a soft tissue," given its broadest reasonable possible interpretation, is construed to overlap with the patient population of Znaiden et al. (col. 1, lines 16-61). Specifically, Znaiden et al. teach that a number of physiological circumstances may contribute to the formation of aberrant arterioles and, in some cases, they are the symptomatic of a systemic, pathological disorder (col. 1). Znaiden et al. also teach that and that the likelihood of developing spider veins increases age and normally occur in about 15 percent of the

population as a cosmetic manifestation not prompted by a specific ailment, especially when the affected vessels are located on the face, upper trunk, lower leg, or other normally visible parts of the body (col. 1). To the extent that the risk of developing spider veins increases with age, the targeted population of the instant application reasonably overlap with the treatment population of Znaiden et al. as evidenced by the teaching of that the risk of atherosclerosis increases with age (Howard et a. Does the association of risk factors and atherosclerosis change with age? An analysis of the combined ARIV and CHS cohonrs. Stroke. 1997;28:1693-1701).

3) An amount of phytate composition that is effective to treat spider veins when applied to the skin would impliedly be absorbed through the skin and ultimately reach the blood stream. Applicant's assertion to the contrary is not convincing and lacks support.

4) It is noted that new claim 14 recites the term "prevention of the development of calcifications in a soft tissue of a patient," which given its broadest reasonable possible interpretation, which is construed to read patients with or without calcifications in the soft tissue who are treated topically with myo-inositol hexaphosphate because the term "prevention" means absolute absence/eradication of calcification from tissue.

Enablement rejection under 112, 1st para

This rejection is being maintained as applicant's arguments as set forth in the response, received 2/5/08, at pages 7-10, are not found to be persuasive for the reasons previously made of record and for the additional reasons:

1) The scope of the claims is still very broad. For example, the term “treatment of a disease associated with the development of calcifications in a soft tissue" and the term "a composition comprising an effective amount of myo-inositol hexaphosphate” are very broad. Specifically, it is not clear how topical administration of a composition comprising an effective amount of myo-inositol hexaphosphate could prevent hypertension, diabetes, or atherosclerosis, or treat diabetes and/or hypertension in a patient even though these are risk factors for the development of plaque in the walls of blood vessels.

2) It is noted that new claim 14 recites the term "prevention of the development of calcifications in a soft tissue of a patient," which given its broadest reasonable possible interpretation, is construed to read on any and all patients with soft tissue who are treated topically with myo-inositol hexaphosphate because the term “prevention” means absolute absence/eradication of calcification from tissue.

REJECTIONS

Claim Rejections – 35 USC 112 – First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabling for methods of preparing and methods of use of myo-inositol compositions for treating certain ectopic diseases associated with the development of heterogenous nucleants which induce the development of pathological calcification in a soft tissue, does not reasonably provide enablement for preventing said diseases and/or treating any and all diseases associated with the development of calcification in a soft tissue. This is a scope of enablement rejection.

To be enabling, the specification of the patent application must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1561 (Fd. Cir. 1993). Explaining what is meant by "undue experimentation," the Federal Circuit has stated that:

The test is not merely quantitative, since a considerable amount of experimentation is permissible, if its is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth in *In re Wands,* 8 USPQ2d 1400 (CAFC 1988) at 1404 wherein, citing *Ex parte Forman* 230 USPQ 546 (BdApls 1986) at 547 the court cited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence or absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art,

7) the predictability of the art, and

8) the breadth of the claims

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. *In re Fisher*, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the Wands factors are relevant to the instant fact situation for the following reasons:

1. The nature of the invention, state and predictability of the art, and relative skill of those in the art.

The invention in general relates to a method of treatment of a disease associated with the development of calcifications in a soft tissue comprising topically administering to a patient having such disease, a composition comprising an effective amount of myo-inositol hexaphopshate, wherein said myo-inositol hexaphosphate can be absorbed by the skin, passing into the blood stream and acting on the damaged zone.

The relative skill of those in the art is high, generally that of an M.D. or Ph.D. It is noted that the chemical and medical arts are generally unpredictable, requiring each embodiment to be individually assessed for chemical, pharmacologic, pharmaceutical, and clinical efficacy. The more unpredictable an area, the more specific enablement is necessary in order to satisfy the statue. (see *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970)).

Grases et al. teach that pathological calcification in soft tissues (i.e.ectopic clacification) can have severe consequences when it occurs in vital organs such as the vascular or renal systems (Grases et al. Effect of crystallization inhibitors on vascular clacifcaqtions induced by vitamin D : A Pilot study in Sprague-Dawley rats. Cir. J. 2007;71:1152-1156; see especially page 1152, col. 1, first para.). Grases et al. teach that in general, the development of tissue clacification requires a preexisting injury as an inducer (heterogenous nucleant), whereas further progression requires the presence of other promoter factors (such as hypercalcemia and/or hyperphosphatemia) and/or a deficiency in calcification repressors factors (crystallization inhibitors and cellular defense mechanisms); see page 1152, col. 1, second para.). Grases et al. teach that pyrophosphate, biphosphonates and phytate (myo-inositol hexakisphosphate) have been shown to inhibit crystallization in the form of vascular calcification (page 1152, col. 2, last para.). Grases et al. also teach that based on the fact that phytate was found to act as vascular calcification inhibitor, the action of polyphosphates could be important in protecting against vascular calcification (page 155, last para.).

2. The breadth of the claims

The instant claims are relatively broad in scope. For example, claim 8 recites the terms “treatment of a disease associated with the development of calcifications in a soft tissue,” “effective amount,” and “damaged zone” which are very broad. Claim 14 recites the term "prevention of the development of calcifications in a soft tissue of a patient" which encompasses the prevention of pathological and normal physiologic processes of calcification.

Because the therapeutic response to be achieved would reasonably vary depending upon the specific mammalian specie, or targeted soft tissue, or location of the soft tissue, or the specific disease associated with the development of calcifications, the level of predictably in practicing the claimed invention would be greatly diminished.

3. The amount of direction or guidance provided and the presence or absence of working examples

The specification discloses study results involving the topical administration of phytate to rats (pages 6-10). Based on the instant disclosure, the applicant at best has provided specific direction or guidance only for a general method of treating ectopic calcifications. Further, extrapolation of the exemplified rat data disclosed by applicant to any and all mammalian species would reasonably require extensive experimentation in order to achieve the contemplated treatment effects in practicing the instant claimed invention commensurate the claims.

4. The quantity of experimentation necessary

In view of the uncertainty and unpredictability of the art as evidenced by the discussion of the prior art, it is reasonable to surmise that this level of uncertainty in

the art would require one skilled in the art to conduct more than routine experimentation in order to practice the claimed invention commensurate with the scope of the claims.

For the reasons stated above, claims 8-19 are rejected under 35 USC 112, first paragraph, for lack of scope enablement because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with the claims.

Claim rejections – 35 USC 112 – Second Paragraph

The following is a quotation of the second paragraph of 35 USC 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8, and 14 recite the term “effective amount of myo-inositol hexaphosphate,” which renders the claim indefinite because said term could be reasonably interpreted to have two or more completely different meanings. For example, the term could mean an effective amount that is pharmaceutically suitable for topical application, or an effective amount to prevent the development of calcifications in soft tissue, or an effective amount to treat a condition associated with the development of calcifications.

Dependent claims 9-13, and 15-19 are rejected for the same reason as these claims fail to correct the deficiency of the claims from which depend.

Claim rejections – 35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8-19 are rejected under 35 USC 102(b) as being anticipated by Znaiden et al. (US Patent Application 5,268,176).

Znaiden et al. teach topical compositions containing inositol hexaphopshate (phytic acid or myo-inositol) for use in the treatment of telangiectasia (or spider veins), which is characterized by the visual dilation of one or more superficial skin arterioles in the human body (col. 1, line 16 to col. col. 4, line 46).

To the extent that the risk of developing spider veins increases with age, the targeted population as encompassed by claims 8-13 reasonably overlap with the treatment population of Znaiden et al. as evidenced by the teaching that the risk of atherosclerosis increases with age (Howard et a. Does the association of risk factors and atherosclerosis change with age? An analysis of the combined ARIV and CHS

cohonrs. Stroke. 1997;28:1693-1701). Also, the treatment population of Znaiden et al. overlaps with the targeted population encompassed by claims 14-19 as the term "prevention of the development of calcifications in a soft tissue of a patient" as recited in claim 14, given its broadest reasonable possible interpretation, reads on patients with or without calcifications in the soft tissue who are treated topically with myo-inositol hexaphosphate as the term “prevention” means absolute absence/eradication of calcification from soft tissue.

The limitations recited in claims 9-13 and 15-19 (e.g. “wherein the soft tissue is subepithelial tissue” as recited in claim 9, for example; “wherein the soft tissue is renal tissue” as recited in claim 10, for example; “wherein the soft tissue is pulmonary tissue” as recited in claim 11, for example; “wherein the soft tissue is cerebral tissue” as recited in claim 12, for example; wherein the soft tissue is the wall of blood vessel” as recited in claim 13, for example) are construed to be inherent characteristics of practicing the claimed method as these recited soft tissues are present in all patients and drugs, once absorbed, get distributed via the blood, which reasonably is in contact with the recited soft tissues and thereof are not construed to confer patentable weight to the claimed method.

Thus, claims 8-19 are found to be anticipated by the instant claims.

Claim rejections – 35 USC 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Alternatively, claims 8-19 are rejected under 103(a) as being unpatentable over Znaiden et al. (US Patent Application 5,268,176).

The above discussion in connection with the rejection under 102(b) is incorporated by reference.

Based on the teachings of Znaiden et al., someone of skill in the art would have deemed it obvious to create the instant claimed invention with reasonable predictability, albeit for treating spider veins, as the contemplated effect to be achieved in practicing the instant claimed invention are coextensive in applying an effective amount of a composition comprising myo-inositol to the skin.

Relevant Art of Record

The below cited art made of record and relied upon is considered pertinent to applicant's invention.

Galvin et al. (US Patent 6,359,194) teach methods for screening compounds and other substances for treating cardiovascular disease symptoms, including cardiac calcification, hemorrhagic telangiectasia, advanced atherosclerosis and/or plaque rupture, cardiovascular calcification (col. 8, line 64 to col. 9, line 22).

Hippocrates et al. report that five patients on maintenance hemodialysis for more than five years, who had tumoral calcifications, were treated by sodium thiosulfate. Four patients with periarticular and soft-tissue calcifications achieved regression of varying degrees and the motion of the adjacent joints was considerably improved (Hippocrates et al. Sodium thiosulfate treatement of soft-tissue calcifications in patients with end-stage renal disease. Perit Dial Int. 1987;7(4):250-252, abstract only). The fifth patient had calcification of penis; sodium thiosulfate produced early relief of symptoms and later complete disappearance of the calcification.

Steidl et al. teach a method of treating patients suffering from myositis ossifications traumatica comprising local application of magnesium sulfate under local anesthesia into calcified areas for 2-20 weeks (Steidl et al. Soft tissue calcification treated with local and oral magnesium therapy. Magnes Res. 1990;3(2):113-9, abstract only). Steidl et al. teach that said treatment resulted in the disappearance or substantial reduction of the soft tissue calcifications (abstract).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charlesworth Rae whose telephone number is 571-272-6029. The examiner can normally be reached between 9 a.m. to 5:30 p.m. Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http:pair-direct.uspto.gov.

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24 April 2008

/C. R./

Examiner, Art Unit 1611

/Brian-Yong S Kwon/
Primary Examiner, Art Unit 1614